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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,835	08/17/2006	Jamey Marth	19452A-003110US	3683

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,835	MARTH ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *14-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-13 in the reply filed on March 25, 2009 is acknowledged. Applicant argues that the present claims relate to a single inventive concept, namely the use of inhibiting ST8Sia-II sialyltransferase activity for ameliorating an anxiety response. This is not found persuasive because while the claim recites a method that involves the use of alternative agents that can inhibit ST8Sia-II sialyltransferase activity, they do not appear to meet the required criteria for a proper Markush group, thereby conferring unity of invention. These criteria are:

(A) all alternatives have a common property or activity, *and*

(B)(1) a common structure is present, that is a significant structural element is shared by all the alternatives, *or*

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the instant case, according to the specification, all agents need not even have the same common property. The specification appears to describe a method that embraces "inhibition of ST8Sia-II sialyltransferase activity" by (1) direct inhibition of ST8Sia-II sialyltransferase; (2) inhibition of gene expression; or (3) blocking polysialic acid binding. At a macro level, they may have the same ultimate result, these agents act very differently at the mechanistic level. Furthermore, even if the method were limited to one of these methods of inhibition, direct

enzyme inhibition, for example, some common ST8Sia-II sialyltransferase inhibitors are (1) CMP-sialic acid derivatives and (2) soyasaponins. Structurally, these are very different and are not in a common class of compounds. And these are just the currently known inhibitors—the claims embrace the use of any and all that might be discovered.

The requirement is still deemed proper and is therefore made FINAL. Claims 14-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of ameliorating an anxiety response in a mammal in need thereof comprising administration of a compound that inhibits ST8Sia-II sialyltransferase activity. It appears that "anxiety response" is an art-recognized term. See Calvo et al (Motivation and Emotion, 1998) at page 212, 1st full paragraph. However, this appears to be a symptom, but a dependent claim recites "wherein the anxiety response comprises depression." This is

problematic for at least two reasons. First of all, it appears that the method recites that the symptom comprises the disease. Furthermore, if what is meant is an "anxiety disorder" rather than the "anxiety response," "depression" and "anxiety disorder" are differently classified disorders. Perhaps what is intended in claim 13 is co-morbid anxiety and depressive disorders. Or, it could be the treatment of some behavioral disorder having an anxiety response component. Or, it could be something else not contemplated by the examiner. The claims are thus rendered vague and indefinite, so that one of ordinary skill would not be apprised of the metes and bounds of the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);
(2) The amount of direction or guidance presented;
(3) The presence or absence of working examples of the invention;
(4) The nature of the invention;
(5) The state of the prior art;
(6) The relative skill of those in the art;
(7) The predictability or unpredictability of the art; and
(8) The breadth of the claims.

As discussed above, there is some question as to the precise scope (breadth) of the instant method, but the method is drawn, in some manner, to the amelioration of "an anxiety response."

Current pharmacological treatment of anxiety disorders comprises the use of agents having a direct effect on neurotransmitters, such as GABA, serotonin and norepinepherine. See, for example, Sramek et al (Drugs, 2002) at section 3. Applicant has not demonstrated any particular effect on these neurotransmitters by the inhibition of ST8Sia-II sialyltransferase activity.

The basis of the mode of action in the instant method does not appear to be related to any currently used therapy for the treatment of anxiety disorders. Applicant has observed that an animal with an inactivated ST8Sia-II gene has a phenotype exhibiting increased exploratory behavior and reduced fear conditioning responses. From this Applicant hypothesizes that inhibition of expression of this gene or inhibition of the gene product will ameliorate an anxiety response.

Applicant provides no working examples for this method. The disclosure suggests dosage ranges of about 1.0 mg to about 10 g to a 70 kg patient. This is a generic dosage spanning four orders of magnitude for undescribed compounds that may work in very different ways. This is essentially no guidance.

Millan (Prog. Neurobiol., 2003) reviews the state of the art with respect to the control of anxious states, which are induced and inhibited through a diversity of mechanisms. (See abstract) Experimental study of anxiety is difficult for a variety of reasons. One is the absence of surrogate markers that may be objectively measured. (See section 1.3.) Section 18 comprises a discussion of future research directions. Section 18.6 discusses genetic approaches, including knock-out, as

in the instant disclosure. The first paragraph of this section outlines the difficulties in extrapolating knock-out phenotypes to clinical treatment. Finally, Section 18.10 states "In view of the intricate and dynamic pattern of reciprocal interactions amongst mechanisms controlling anxious states, the clinical consequences of their manipulation are difficult to predict." Even with useful experimental models, "considerable caution should be exercised in extrapolating hypotheses to man."

Clement et al (Brain Res. Bull., 2002) reviews the state of the art with respect to the genetic basis of anxiety-like behavior. This reference further discusses the difficulties with genetic targeting, per se, and extrapolating the results of this targeting to clinical treatment. See section spanning pp 60-63. The reference concludes with a statement regarding the complexity of anxiety with multiple interactions between genetic and environmental factors.

In view of the forgoing—particularly the complexity and unpredictability in the art combined with the lack of guidance from the disclosure—it is concluded that one of ordinary skill would require undue experimentation comprising great expenditures of time and money in order to use this invention.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:30 to 4:00 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Leigh C. Maier/
Primary Examiner, Art Unit 1623